

Application No.: 10/664,454  
Response dated March 18, 2009  
Reply to Office Action of January 22, 2009  
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### **REMARKS**

Claims 1-27 and 48-55 were previously pending in this application. Through this amendment, independent claims 1 and 27 have been amended to recite that the pocket has been pre-treated with a surfactant to aid in incorporating the fluid into the pocket. Support for this amendments may be found, for example, at paragraph [0078] of the application as filed. Claims 52 and 53 have been canceled. In view of these amendments and the corresponding remarks below, reconsideration of the rejections of the Office Action is respectfully requested.

#### **Claim Rejection Under 35 U.S.C. §102(b)**

The Examiner has rejected claims 1-10, 13-15, 27, 48, 50, 54 and 55 under 35 U.S.C. 102(b) as allegedly anticipated by Houser et al. (U.S. Patent No. 6,149,681). The Examiner has stated that Houser discloses the composite device having a first polymeric layer, a second polymeric layer, and an intermediate structural member therebetween. The Examiner further alleged that Houser disclosed the first liner bonded to the second liner through the openings to form a pocket, the pocket containing a fluid containing a bioactive agent.

The Applicant respectfully disagrees with the Examiner's interpretation of Houser, noting that Houser specifically requires that the pocket (158) be formed between the spaced sections of the support member (160 and 162), and not by the area of direct bonding or joining together of the first liner and the second liner as presently claimed. Despite this interpretation, however, in an effort to further prosecution of this application, the Applicant has amended claims 1 and 27 to recite that the pocket has been pre-treated with a surfactant to aid in incorporating the fluid into the pocket.

As acknowledged by the Examiner, Houser does not disclose or suggest pre-treating the pocket (See, Office Action at page 6). Since Houser fails to disclose each and every limitation of the pending claims, it is respectfully submitted that the claims are patentable over Houser. Withdrawal of the rejection is therefore requested.

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**Claim Rejection Under 35 U.S.C. §103(a)**

The Examiner has rejected claim 11 under 35 U.S.C. 103(a) as allegedly obvious over Houser in view of Rudakov et al. (U.S. Patent No. 6,451,050). The Examiner relied upon Rudakov for disclosing the bioactive agent encapsulated in a polymeric matrix. As explained above, Houser fails to disclose that the drug-containing pocket is pre-treated with a surfactant to aid in incorporating the fluid into the pocket. Rudakov does not disclose any pre-treatment with a surfactant, and thus fails to remedy the defect of Houser. As such, dependent claim 11 is patentable over Houser and Rudakov, whether taken alone or in combination. Withdrawal of this rejection is respectfully requested.

The Examiner then rejected claim 12 under 35 U.S.C. 103(a) as allegedly obvious over Houser in view of Rudakov and further in view of Helmus (U.S. Publication No. 2002/0032477). The Examiner relied upon Helmus for the disclosure of a biological prosthesis that uses microparticles in a matrix. As explained above, Houser fails to disclose that the drug-containing pocket is pre-treated with a surfactant to aid in incorporating the fluid into the pocket. Rudakov does not disclose any pre-treatment with a surfactant, and thus fails to remedy the defect of Houser. Helmus does not disclose any pre-treatment with a surfactant, and thus fails to remedy the defect of Houser and Rudakov. As such, dependent claim 12 is patentable over Houser, Rudakov and Helmus, whether taken alone or in combination. Withdrawal of this rejection is respectfully requested.

The Examiner also rejected claims 16 and 21-26 under 35 U.S.C. 103(a) as allegedly obvious over Houser in view of Golds et al. (U.S. Patent No. 6,001,125). The Examiner relied upon Golds for disclosing a vascular graft constructed from porous ePTFE. As explained above, Houser fails to disclose that the drug-containing pocket is pre-treated with a surfactant to aid in incorporating the fluid into the pocket. Golds does not disclose any pre-treatment with a surfactant, and thus fails to remedy the defect of Houser. As such, dependent claims 16 and

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21-26 are patentable over Houser and Golds, whether taken alone or in combination.

Withdrawal of this rejection is respectfully requested.

The Examiner then rejected claim 17 under 35 U.S.C. 103(a) as allegedly obvious over Houser in view of Buirge et al. (U.S. Patent No. 5,693,085). The Examiner relied upon Buirge for the disclosure of using a biological prosthesis that uses a natural polymer. As explained above, Houser fails to disclose that the drug-containing pocket is pre-treated with a surfactant to aid in incorporating the fluid into the pocket. Buirge does not disclose any pre-treatment with a surfactant, and thus fails to remedy the defect of Houser. As such, dependent claim 17 is patentable over Houser and Buirge, whether taken alone or in combination. Withdrawal of this rejection is respectfully requested.

The Examiner also rejected claim 18 under 35 U.S.C. 103(a) as allegedly obvious over Houser in view of Yan (U.S. Patent No. 6,240,616). The Examiner relied upon Yan for the disclosure of using a bioabsorbable polymer. As explained above, Houser fails to disclose that the drug-containing pocket is pre-treated with a surfactant to aid in incorporating the fluid into the pocket. Yan does not disclose any pre-treatment with a surfactant, and thus fails to remedy the defect of Houser. As such, dependent claim 18 is patentable over Houser and Yan, whether taken alone or in combination. Withdrawal of this rejection is respectfully requested.

The Examiner also rejected claims 19-20 under 35 U.S.C. 103(a) as allegedly obvious over Houser in view of Rhodes (U.S. Patent No. 5,665,117). The Examiner relied upon Rhodes for the disclosure of using stainless steel or tantalum to construct the support member. As explained above, Houser fails to disclose that the drug-containing pocket is pre-treated with a surfactant to aid in incorporating the fluid into the pocket. Rhodes does not disclose any pre-treatment with a surfactant, and thus fails to remedy the defect of Houser. As such, dependent claims 19-20 are patentable over Houser and Rhodes, whether taken alone or in combination. Withdrawal of this rejection is respectfully requested.

The Examiner rejected claims 49 and 51 under 35 U.S.C. 103(a) as allegedly obvious over Houser in view of Yang et al. (U.S. Publication No. 2002/0062147). The Examiner relied upon Yang for the disclosure of using a gel to contain the bioactive agent. As explained above, Houser fails to disclose that the drug-containing pocket is pre-treated with a surfactant to aid in incorporating the fluid into the pocket. Yang does not disclose any pre-treatment with a surfactant, and thus fails to remedy the defect of Houser. As such, dependent claims 49 and 51 are patentable over Houser and Yang, whether taken alone or in combination. Withdrawal of this rejection is respectfully requested.

Finally, in the Office Action, the Examiner rejected claims 52 and 53 under 35 U.S.C. §103(a) as allegedly obvious over Houser in view of Wang et al. (U.S. 6,458,867). The Examiner acknowledged that Houser fails to disclose pre-treating the pocket, and relied upon Wang for its disclosure of pre-treating medical devices for the “purpose of reducing irritation caused by the device”. The Examiner alleged that it would have been obvious to pre-treat as disclosed in Wang to arrive at the claimed invention.

The claims of the present application have been amended. Specifically, claims 52 and 53 have been canceled, and independent claims 1 and 27 have been amended to recite that the pocket has been pre-treated with a surfactant to aid in incorporating the fluid into the pocket. Wang fails to disclose or suggest that the medical device is pre-treated with a surfactant. In fact, Wang’s disclosure is specifically related to lubricants for medical devices, not surfactants. Wang specifically states that the medical devices may be pretreated with “crosslinkable silicones, such as silane or silicone oligomers.” (Col. 12, lines 8-10). In addition to silicones, Wang discloses that other crosslinkable chemical agents may be used “providing that they contain substituents to form hydrogen bonding with the hydrophilic polymer.” (Col. 12, lines 11-13). Wang states that the amount of silicone used may be minimal, “reducing the possibility of irritation to sensitive tissues.” (Col. 12, lines 14-15).

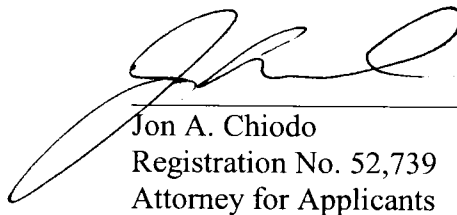
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Thus, Wang's device may only be treated with silicones or other specific crosslinkable chemical agents that can form hydrogen bonding with hydrophilic polymers. Wang does not disclose pre-treating a medical device with a surfactant. Specifically, Wang does not disclose pre-treating a medical device with a surfactant to aid in incorporating the fluid into the pocket. As is readily understood by one of skill in the art, a surfactant may be used to lower the surface tension of the fluid, allowing spreading. The surfactant is used in the present claims to allow for more full and complete filling of the pocket. Wang's pretreatment is for the purpose of lubrication, not for aiding in filling the pocket, and does not include a surfactant. One of skill in the art would not be led to use a silicone pretreatment step to aid in incorporating the fluid into the pocket.

Neither Houser nor Wang discloses that the pocket has been pretreated with a surfactant. As such, the claims of the pending application are allowable over Houser and Wang, whether taken alone or in combination. Withdrawal of this rejection is respectfully requested.

Applicant has responded in full to the present Office Action. Favorable action is respectfully solicited. Should the Examiner have any questions or comments concerning this Response, the Examiner is respectfully invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,



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